

placed over a cast to protect it from getting wet during a shower or a bath.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38806, July 25, 2001]

§ 880.6190 Mattress cover for medical purposes.

(a) *Identification*. A mattress cover for medical purposes is a device intended for medical purposes that is used to protect a mattress. It may be electrically conductive or contain a germicide.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 59 FR 63011, Dec. 7, 1994; 66 FR 38806, July 25, 2001]

§ 880.6200 Ring cutter.

(a) *Identification*. A ring cutter is a device intended for medical purposes that is used to cut a ring on a patient's finger so that the ring can be removed. The device incorporates a guard to prevent injury to the patient's finger.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice require-

ments of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38806, July 25, 2001]

§ 880.6230 Tongue depressor.

(a) *Identification*. A tongue depressor is a device intended to displace the tongue to facilitate examination of the surrounding organs and tissues.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38806, July 25, 2001]

§ 880.6250 Patient examination glove.

(a) *Identification*. A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

(b) *Classification*. Class I (general controls).

[45 FR 69682-69737, Oct. 21, 1980, as amended at 53 FR 1604, Jan. 13, 1989; 66 FR 46952, Sept. 10, 2001]

§ 880.6260 Filtering facepiece respirator for use by the general public in public health medical emergencies.

(a) *Identification*. A filtering facepiece respirator for use by the general public in public health medical emergencies is a device that is a disposable half-facepiece non-powered air-purifying particulate respirator intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates

§ 880.6265

during a public health medical emergency. The device is made of polymeric materials and is intended to fit closely to the face and to function by filtering particulate material.

(b) *Classification.* Class II (special controls). The special controls are:

(1) Certification by the National Institute for Occupational Safety and Health (NIOSH) as a non-powered air-purifying particulate respirator with a minimum filtration efficiency classification of N95, in accordance with 42 CFR part 84.

(2) The FDA guidance document entitled: “Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Filtering Facepiece Respirator for use by the General Public in Public Health Medical Emergencies.” See §880.1(e) for information on obtaining a copy of this guidance document.

[72 FR 36362, July 3, 2007]

§ 880.6265 Examination gown.

(a) *Identification.* An examination gown is a device intended for medical purposes that is made of cloth, paper, or other material that is draped over or worn by a patient as a body covering during a medical examination.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38806, July 25, 2001]

§ 880.6280 Medical insole.

(a) *Identification.* A medical insole is a device intended for medical purposes that is placed inside a shoe to relieve the symptoms of athlete’s foot infection by absorbing moisture.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in

21 CFR Ch. I (4–1–12 Edition)

subpart E of part 807 of this chapter, subject to the limitations in §880.9.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 54 FR 25050, June 12, 1989; 66 FR 38806, July 25, 2001]

§ 880.6300 Implantable radiofrequency transponder system for patient identification and health information.

(a) *Identification.* An implantable radiofrequency transponder system for patient identification and health information is a device intended to enable access to secure patient identification and corresponding health information. This system may include a passive implanted transponder, inserter, and scanner. The implanted transponder is used only to store a unique electronic identification code that is read by the scanner. The identification code is used to access patient identity and corresponding health information stored in a database.

(b) *Classification.* Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information.” See §880.1(e) for the availability of this guidance document. This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §880.9.

[69 FR 71704, Dec. 10, 2004]

§ 880.6310 Medical device data system.

(a) *Identification.* (1) A medical device data system (MDDS) is a device that is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices:

(i) The electronic transfer of medical device data;

(ii) The electronic storage of medical device data;

(iii) The electronic conversion of medical device data from one format to another format in accordance with a preset specification; or

(iv) The electronic display of medical device data.

(2) An MDDS may include software, electronic or electrical hardware such